F. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

SUBMITTER:	Manoa Medical, Inc. 1017 El Camino #361 Redwood City, CA 94063 Phone: 408-666-1413 Fax: 650-365-8340
CONTACT PERSON:	Niyazi Beyhan
DATE PREPARED:	September 30, 2003
CLASSIFICATION NAME:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 870.4400)
COMMON NAME:	Breast biopsy device
PROPRIETARY NAME:	Not Yet Determined
PREDICATE DEVICES:	Rubicor Medical, Inc.: EnCapsule Ethicon-Endosurgery: Mammotome Hand-Held SenoRx: Easy Guide Valleylab: Coated Electrodes Imagyn: SiteSelect
DEVICE DESCRIPTION:	The Manoa Breast Biopsy System is comprised of a sheath introducer, a tissue cutter, a specimen retriever and an electrosurgical cable. The Manoa Breast Biopsy System is a minimally invasive biopsy device designed to penetrate, cut and collect an intact tissue specimen during a biopsy procedure.
INDICATIONS FOR USE:	The Manoa Breast Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure. It is for diagnostic purposes only and is not intended for therapeutic use.
MATERIALS:	The Manoa Breast Biopsy System is composed of biosafe materials which are ISO 10993-1 compliant for their intended patient contact profile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

Roberta Lee, M.D.
Founder & CEO
Manoa Medical, Inc.
1017 El Camino PMB 361
Redwood City, California 94063

Re: K033205
Trade/Device Name: Manoa Breast Biopsy System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 29, 2003
Received: January 2, 2004

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

E. Indications for Use

510(k) Number (if known): K033205

Name: Manoa Breast Biopsy System

Indications for Use:

The Manoa Breast Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure. It is for diagnostic purposes only and is not intended for therapeutic use.

Prescription Use: ___X___ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033205

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____